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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,607	12/12/2001	Darcy Wayne Greep	14458.41	7181

22913 7590 08/29/2003

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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,607

Applicant(s)

GREEP ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-24 and 26-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This is a supplemental office action. There are new rejections directed to the claims that pertain recited "amphophilic" material subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24, 26-38, 42 and 44-47 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 17-58, 61 and 73 of copending Application No. 10/021532. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the product and method of coating an electrosurgical tip that deal with either a hydrophilic/hydrophobic mix polymer or a

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water-soluble polymer. Other than this difference, which is not a major distinction, the dependent claims read almost identically.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 37-41 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “amphophilic” in claims 6, 37-41 and 43 is used by the claims to mean, or rather give “an example of a multi-character material” see page 8, last line of ¶ 27, while the accepted meaning is a chemical compound “stainable with either acid or basic dyes.” The term is indefinite because the specification does not clearly redefine the term.

The examiner suggests changing “amphophilic” to –amphiphilic--.

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The generally accepted meaning of amphiphilic is a substance having the existence of distinct polar (hydrophilic) and non polar (hydrophobic) regions in the molecule promotes the formation of micelles in dilute aqueous solution.

For the purposes of examination, the examiner interprets “amphophilic” as “amphiphilic” and that it is denoted as “a substance having the existence of distinct polar (hydrophilic) and non polar (hydrophobic) regions in the molecule promotes the formation of micelles in dilute aqueous solution.”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-23, 26-31 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garito et al. (USPN 4,754,754) in view of Jones et al. (USPN 6,132,427) in further view of Fan et al. (USPN 5,295,978).

Regarding claim 1,2, 4, 7, 11, 14, 17, 22, 29 and 30, Garito et al. disclose the claimed invention including an “RF output socket” (11) and a hand piece (20), see col. 2, lines 49-68. Garito et al. fail to disclose a multi character coated electrode tip. Jones et al. teach the method, step or use of a device including a multi-layered coated tip electrode with a base coating (16) of ceramic in order to provide a wear resistant cover, see col. 3, lines 4-

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31. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Additionally, Fan et al. teach the method, step or coating of with a water-soluble polymer material which "becomes lubricious when exposed to body fluid". The fact that Fan et al. disclose a coating having hydrophilic material that can be interpreted as attracting water and Applicant's assertion on page 9, ¶ 030, lines 4-8, that a multicharacter material that attracts water to the surface and lubricates the surface creates a low shear, sacrificial layer. The recitation of lubricious nature of the polymer coating meets the claimed limitation. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings and to use a polymeric coating that becomes lubricious when exposed to body fluid in order to provide improved coating performance.

Regarding claim 3, Garito et al. in view of Jones et al. disclose the claimed invention, see col. 4, lines 13-23.

Regarding claims 5, 15, 18, 23 and 31, Garito et al. disclose the claimed invention except for the pores base material wherein the multi-character material occupies at least a portion of the pores. Jones et al. teaches the inclusion of a conductive tip comprising a porous metal of roughened stainless steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. The hydrophilic/hydrophobic material of Fan et al. will inherently occupy the pores. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the inclusion of a conductive tip comprising a porous metal of roughened stainless steel to the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers that inherently occupy the pores in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings.

Regarding claim 6, Garito et al. in view of Jones et al. (USPN 6,132,427) in further view of Fan et al. disclose the claimed invention. The accepted meaning of "amphiphilic" is interchangeable with applicant's disclosed meaning of multicharacter material (see page 8, last line of ¶ 27).

Regarding claims 8, 9 and 21, Garito et al. in view of Jones et al. disclose the claimed invention except for the water-soluble polymer comprising at least one of polyethylene oxide, polyethylene glycol or a copolymer of ethylene oxide. Fan et al. teach a method and use of “poly(ethylene oxide)” as the water-soluble polymer (an atom polymer) in order to overcome the shortcomings of earlier coating polymers, see col. 3, lines 28-43. Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al. in view of Jones et al., as taught by Fan et al. to use “poly(ethylene oxide)” as the water-soluble polymer in order to overcome the shortcomings of earlier coating polymers.

Regarding claims 10, 24 and 42, Jones et al. disclose the claimed invention except for the water soluble polymer having “a radical scavenger that reduces damage to the base layer material during a process of gamma sterilization.” Fan et al. teach a method and use of providing a large number of coatings and their equivalence, including a polymer coating containing “organic radicals,” see col. 5, lines 7-66. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Jones et al., as taught by Fan et al., to alternately use a large number of polymer coatings some including “organic radicals.” The examiner interprets radical scavengers, organic radicals and a radical as the same, i.e., a chemical unit that functions as a single unit, is chemically inalterable and has an unpaired electron. Since Fan et al. disclose so many alternative polymer coatings (as does Applicant), the disclosure of Fan et al. actually teaches an equivalence of the variety of polymer coatings. Additionally,

the phrase “that reduces damage to the base layer material during a process of gamma sterilization” is intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claims 12, 13, 27 and 28 Garito et al. in view of Jones et al. disclose the claimed invention except for the inclusion of carrying deposits of a factor that further includes at least one of an antibiotic, a healing, an anti-adhesion, an anti-tumor or a tumor necrosis factor. Fan et al. teaches the use biocompatible polymeric abrasion resistant surfaces including formulated additives with antimicrobial or other pharmaceutically effective agents” in order to overcome the shortcomings of earlier coatings and provide a more varied method and wider range of coatings and their properties, see col. 2, lines 43-68. Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al in view of Jones et al., as taught by Fan et al. to use biocompatible polymeric abrasion resistant surfaces with included formulated additives with antimicrobial or other pharmaceutically effective agents” in order to overcome the shortcomings of earlier coatings and provide a more varied method and wider range of coatings and their properties.

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Regarding claims 16 and 26, Garito et al. in view of Jones et al. disclose the claimed invention except for using a multi-character material that includes a charged unit. Fan et al. teach the method, step or device that includes a metallic or ammonium ion, co. 5, lines 41-68 and col. 6, lines 1-3.

Regarding claims 19 and 20, Garito et al. in view Jones et al. disclose the claimed invention that includes a conductive tip comprising a porous metal of roughened stainless steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25. Furthermore, Jones et al. disclose a method of applying the ceramic coating layer over top the roughened substrate by spraying using a plasma gun. Therefore, the ceramic coating layer is inherently porous since it lies atop the roughened substrate.

Regarding claim 36, Garito et al. in view of Jones et al. disclose the claimed invention except for the multi-character material coating and the coating application process comprising a, dip, spray, brushing, wiping or adsorption process. Fan et al. teach the use of a hydrophilic/hydrophobic polymeric combination material and a coating application process by dipping, claims 1 and 5 and col. 11, lines 44-54. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al. in view of Jones et al., as taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers and to coat by using a dipping process in order to provide an abrasion resistant coating to overcome the shortcomings of earlier coatings.

Regarding claim 37, Garito et al. in view of Jones et al. disclose the claimed invention except for the water-soluble polymer comprising at least one of polyethylene oxide, polyethylene glycol or a copolymer of ethylene oxide. Fan et al. teach a method and use of “poly(ethylene oxide)” as the water-soluble polymer (an atom polymer) in order to overcome the shortcomings of earlier coating polymers, see col. 3, lines 28-43. The accepted meaning of “amphiphilic” is interchangeable with applicant’s disclosed meaning of multicharacter material (see page 8, last line of ¶ 27). Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al. in view of Jones et al., as taught by Fan et al. to use “poly(ethylene oxide)” as the water-soluble polymer in order to overcome the shortcomings of earlier coating polymers.

Regarding claim 38, Garito et al. disclose the claimed invention except for the pores base material wherein the multi-character material occupies at least a portion of the pores. Jones et al. teaches the inclusion of a conductive tip comprising a porous metal of roughened stainless steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. The hydrophilic/hydrophobic material of Fan et al. will inherently occupy the pores. The accepted meaning of “amphiphilic” is

interchangeable with applicant's disclosed meaning of multicharacter material (see page 8, last line of ¶ 27). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the inclusion of a conductive tip comprising a porous metal of roughened stainless steel to the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers that inherently occupy the pores in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings.

Regarding claims 39-41 and 43, Garito et al. disclose the claimed invention including an "RF output socket" (11) and a hand piece (20), see col. 2, lines 49-68. Garito et al. fail to disclose a multi character coated electrode tip. Jones et al. teach the method, step or use of a device including a multi-layered coated tip electrode with a base coating (16) of ceramic in order to provide a wear resistant cover, see col. 3, lines 4-31. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Additionally, Fan et al. teach the method, step or coating of with a water-soluble polymer material which "becomes lubricious when exposed to body fluid". The fact that Fan et al. disclose a coating having hydrophilic material that can be interpreted at attracting water and Applicant's assertion on page 9, ¶ 030, lines 4-8, that a

multicharacter material that attracts water to the surface and lubricates the surface creates a low shear, sacrificial layer. The recitation of lubricious nature of the polymer coating meets the claimed limitation. The accepted meaning of “amphiphilic” is interchangeable with applicant’s disclosed meaning of multicharacter material (see page 8, last line of ¶ 27). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings and to use a polymeric coating that becomes lubricious when exposed to body fluid in order to provide improved coating performance.

Response to Arguments

Regarding the issue of a low shear, sacrificial layer, Applicant clearly qualifies a low shear, sacrificial layer as a hydrophilic material that can be interpreted as attracting water and as Applicant asserts on page 9, ¶ 027, lines 9-11, that attracting water to a surface to an otherwise hydrophobic material assists in cooling and lubricating the surface creating a low shear, self-renewing, sacrificial layer. Applicant also asserts that the low shear, self-renewing, sacrificial layer can deposit factors onto one or more contact surfaces, see page 9, ¶ 027, lines 15 and 16 and claims 14 and 15. These deposited factors are interpreted as constituting a layer that may be

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abraded. The disclosure of Fan et al. provides these features and coatings to be layered on medical instruments therefore the combination of Jones et al. and Fan et al. is proper and reaffirmed.

The recitation pertaining to the “amphophilic” nature of the coating material is not distinct over the prior art since the generally accepted meaning of amphiphilic is a substance having the existence of distinct polar (hydrophilic) and non polar (hydrophobic) regions in the molecule promotes the formation of micelles in dilute aqueous solution and the meaning given by Applicant which is “an example of a multi-character material” (see page 8, last line of ¶ 27) are interchangeable.

The action is non final due to the new rejection of the “radical scavenger” and “amphiphilic/(amphophilic) features. This feature should have been rejected in the initial office action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references may prove useful. Allen (USPN 4,314,559), Lontine et al. (USPN 5,713,895) and (USPN 6,139,547) disclose coated substrates containing pores. Both Sansom et al. (USPN 5,197,962) and Morris (USPN 6,106,523) discloses composite coated

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devices and the methods of coating such, while Sutcu et al (USPN 5,549,604) disclose an amorphous silica coating. Finally Fan et al. (USP 5,509,899 5,558,900 and 5,731,087) deal give a fair review of the coating compounds, methods of and improvements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. *A.R.*
August 25, 2003

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER